IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

AMERICAN SALES COMPANY, INC., on behalf of itself and all others similarly situated, Plaintiff, v. SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, PLC, Defendant.	Civil Action No. _____ ECF Case **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT AND JURY DEMAND

Plaintiff American Sales Company, Inc. ("Plaintiff") brings this nationwide class action on behalf of itself and a proposed class of direct purchasers of the prescription drug Flonase and its generic equivalent, fluticasone propionate. Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline plc ("Defendant" or "GSK") unlawfully abused the citizen petition process contained in Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), and thereby fraudulently delayed the introduction of generic – and thus cheaper – versions of the prescription drug Flonase into the United States market, causing injury to Plaintiff and members of the Class. As a result of its anticompetitive conduct and illegal scheme to keep generic versions of Flonase off the market, and in violation of §2 of the Sherman Act, GSK: (a) illegally maintained monopoly power in the market for fluticasone propionate in the United States for twenty (20) months and sold more than $1 billion of Flonase during that time; (b) maintained the price of Flonase at supra-competitive levels; and (c) overcharged Plaintiff and members of the proposed Class of direct purchasers of fluticasone propionate millions of dollars by depriving them of the benefits of unrestricted competition and access to cheaper generic versions of

fluticasone propionate. Plaintiff seeks treble damages resulting from GSK's unlawful behavior.

I. PARTIES

1. Plaintiff American Sales Company, Inc. ("ASC") is a Delaware corporation with its principal place of business in Lancaster, New York. ASC purchases health products, including prescription drugs, for retail stores owned and operated by affiliated companies. During the relevant period, ASC purchased Defendant's Flonase directly from Defendant and was injured as a result of Defendant's misconduct as set forth herein. Plaintiff brings this class action on behalf of itself and a proposed class of direct purchasers of the prescription drug Flonase and its generic equivalent, fluticasone propionate. In this complaint, Plaintiff alleges as follows based on (a) personal knowledge as to matters relating to Plaintiff, (b) the investigation of Plaintiff's counsel, including review of Defendant's citizen petitions and other filings with the United States Food and Drug Administration ("FDA"), and (c) information and belief as to all other matters.

2. Defendant SmithKline Beecham Corporation is a Pennsylvania Corporation with its principal offices located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham also conducts business in the name of GlaxoSmithKline Inc. and is a subsidiary of GlaxoSmithKline plc.

II. JURISDICTION AND VENUE

3. Plaintiff brings this action pursuant to § 4 of the Clayton Act, 15 U.S.C. § 15, to recover threefold damages in the form of overcharges, and the costs of suit and reasonable attorneys' fees, for the injuries sustained by Plaintiff and members of a proposed class of direct purchasers of Flonase resulting from GSK's violation, as alleged herein, of § 2 of the Sherman Act, 15 U.S.C. §2. This Court has jurisdiction over this action based upon 28 U.S.C. §§ 1331

and 1337(a), and 15 U.S.C. §15.

4. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c) in that GSK transacts business in this judicial district.

III. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs

5. Under the FDCA, codified at 21 U.S.C. §§ 301-392, manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

6. In 1984, Congress modified the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The modification, more typically known as the Hatch-Waxman Amendments, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers file an abbreviated application (an "ANDA") which relies in substantial part on the scientific finding of safety and effectiveness included by the brand named manufacturer in the NDA for the same drug. 21 U.S.C. § 355(j).

7. Two primary goals motivated the enactment of the Hatch-Waxman Amendments. First, where a generic product could be developed that did not infringe any existing legitimate patent, Congress sought to expedite the entry of generic competitors and thereby reduce healthcare expenses nationwide. Second, Congress wanted to protect the incentive of pharmaceutical companies to create new and innovative products. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product

launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies.

8. Under the terms of the FDCA and the Hatch-Waxman Amendments, a prospective generic manufacturer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand named drug. 21 U.S.C. § 355(j)(2)(A)(iv). The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another.

9. Bioequivalency demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B). For drugs that are not intended to be absorbed into the bloodstream, including Flonase, the Hatch-Waxman Amendments provide that the FDA "may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect." 21 U.S.C. § 355(j)(8)(C); 21 C.F.R. § 320.24(b)(6).

10. In reviewing what "alternative, scientifically valid methods" it might consider in determining bioequivalence of drugs, the FDA may – but is not required to – issue a guidance document articulating the agency's current thinking on the issue. No regulations require the FDA to issue such a guidance document, however, and guidance documents, where they exist, do not bind either the FDA or the public as they do not establish legally enforceable rights or responsibilities. Rather, the guidance documents are just that – they embody the FDA's current

thinking on a subject and provide guidance to the public. The FDA's obligation to make a determination as to whether an individual ANDA meets statutory requirements and thus should be approved depends in no part on whether or not a guidance document relevant to that ANDA exists.

11. As a counter-balance to this abbreviated approval procedure for bioequivalent generic drugs, the Hatch-Waxman Amendments streamlined the process for brand name manufacturers to enforce legitimate patents they may hold against infringement by generic manufacturers. Beyond traditional patent rights, the Hatch-Waxman Amendments also provide brand name manufacturers with several means to obtain legitimate protection from generic competition for set, and specifically limited, periods of time. For example, each approved NDA provides the owner of that drug with three years of exclusivity during which time no generic manufacturer can even file an ANDA. 21 U.S.C. § 355(j)(5)(F)(iii). Pioneer drugs or truly new or innovative drugs that make use of a never-before-approved chemical entity or moiety receive even more time: a "New Chemical Entity" ("NCE") exclusivity period of five years. 21 U.S.C. § 355(j)(5)(F)(ii).

B. Generic Drugs Offer Significant Savings and Thus Take Significant Sales From Brand Name Drugs

12. Drugs proven to meet bioequivalence requirements through *in vivo* (clinical) and/or *in vitro* (laboratory) testing receive an "AB" rating from the FDA, indicating they are therapeutically equivalent to other drugs with the same rating in the same category. For example, Roxane Laboratories, Inc.'s ("Roxane") fluticasone proprionate is an AB-rated generic version of GSK's Flonase, indicating the drugs are therapeutically equivalent and bioequivalent to one another.

13. Typically, manufacturers of AB-rated generic versions of brand name drugs

price their drugs significantly below the brand name counterparts. Because of the price differential and certain institutional features of the pharmaceutical market which seek to capitalize on this price differential, AB-rated generic versions are rapidly and substantially substituted for their brand name counterparts.

14. Under the statutory regime enacted by Congress (*i.e.*, the Hatch-Waxman Amendments) and as found in most state legislatures (i.e., Drug Product Selection, or "DPS laws"), pharmacists may – and, in most states, must – substitute an AB-rated generic version of a drug for the brand name drug without seeking or obtaining permission from the prescribing doctor.[1] Congress and state legislatures actively encourage generic substitution of brand name drugs because of the enormous cost savings to purchasers and consumers generated.[2]

15. Once a physician writes a prescription for a brand name drug such as Flonase, the prescription defines and limits the options to the named drug and its AB-rated generic equivalent(s). Only drugs which carry the FDA's AB generic rating in that category may be substituted by pharmacists for a physician's prescription for a brand name drug.

16. Generic competition enables the purchase of generic versions of brand name drugs at substantially lower prices. Such competition also results in reduced prices for, and thus savings on purchases of, the brand name drug (as the brand manufacturer lowers prices in an attempt to maintain market share). Prior to entry of an AB-rated generic and competition, however, brand name manufacturers can charge supra-competitive prices without losing all, or a

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[1] The exception to this general rule appears when the prescribing physician indicates "dispense as written" or "DAW" on the prescription. In such instances, pharmacists may not substitute a generic version of the drug.

[2] Federal and state legislatures also recognize that the economics of the pharmaceutical industry prevent generic manufacturers from engaging in the heavy promotion or "detailing" typically done by brand name manufacturers.

substantial portion, of its brand name sales. Consequently, brand name drug manufacturers have strong incentives to delay the introduction of AB-rated generic competition into the market.

C. Citizen Petitions to the FDA

17. Recognizing the central role that healthcare and pharmaceutical drugs play in the United States, Congress enacted federal regulations governing the FDA that allow individuals to express genuine concerns about safety, scientific, or legal issues regarding a product anytime before, or after, its market entry. Under these regulations, any person or entity, including a pharmaceutical company, may file a citizen petition with the FDA requesting that the FDA take, or refrain from taking, any administrative action. 21 C.F.R. 10.30.

18. Within 180 days of receipt, the FDA Commissioner must respond to each citizen petition and may approve the request in part or in full, deny it, or provide a tentative response with an estimate on a time for a full response. 21 CFR 10.30(e)(2).

19. Reviewing and responding to these petitions often requires the use of substantial time and resources because the FDA must, in addition to its already-existing workload: (a) research the subject matter of the citizen petition; (b) examine scientific, medical, legal, and sometimes economic issues; (c) consider public responses to the citizen petition; and (d) coordinate internal agency review and clearance of the petition response. These activities can and do strain the FDA's limited resources.

D. Named Brand Manufacturers Use Citizen Petitions to Forestall Generic Competition

20. In recent years, a number of brand name pharmaceutical manufacturers abused

the citizen petition process, using it as a tactic to extend their monopolies on name brand drugs.[3] Citizen petitions by rival companies rarely raise legitimate concerns about the safety or efficacy of generic products, and instead only seek to preserve monopolies after the end of a statutorily-granted patent or FDA exclusivity period. Companies frequently file these citizen petitions on the eve of FDA approval of an ANDA for competing AB-rated generic drugs, even though the petitioner could have made the same arguments months, or even years, before. This results in delay of final approval of a pending ANDA for several months or more while the FDA evaluates the merits of the citizen petition.

21. The resulting delay of generic competition can be lucrative for an incumbent brand name manufacturer facing impending competition from an AB-rated generic. The cost of filing an improper, sham citizen petition pales in comparison to the value of securing an additional period of monopoly profits.

22. In recent years, only about 7% of citizen petitions regarding the approvability of generic products led to any change in the FDA's policy on the basis of data or information submitted in the petition. Yet prior to 2007, the FDA maintained a practice, well known in the pharmaceutical industry, of considering and responding to relevant citizen petitions prior to approval of an ANDA to assure itself that the petitions did not present any new issues or issues of concern.

23. The abuse of the citizen petition process in part helped lead Congress to enact the FDA Amendments Act of 2007, 21 U.S.C. 355(q) (the "2007 Amendments"). In pertinent part, the 2007 Amendments provide that the FDA shall not delay approval of a pending ANDA

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[3] See Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, at *http://www.ftc.gov/be/v000005.pdf,* at p. 1, *et seq.*

because of a citizen petition unless the FDA determines that a delay is necessary to protect the public health. The 2007 Amendments also authorize the FDA to summarily deny any citizen petition whose primary purpose, as determined by the FDA, is to delay competition. Signed into law on September 27, 2007, these revisions were not yet in effect at the time the FDA was considering the petitions at issue here.

IV. FACTUAL BACKGROUND

A. Flonase

24. GSK manufactures, markets, and sells Flonase, a brand name prescription drug. Flonase, the generic name for which is fluticasone propionate, is a corticosteroid nasal spray used for treatment of nasal symptoms of seasonal and year-round allergies, as well as nonallergic rhinitis in adults and pediatric patients four years of age and older.

25. The active ingredient in Flonase is a corticosteroid: fluticasone propionate. Flonase consists of an aqueous suspension of microfine fluticasone propionate intended for topical administration to the nasal mucosa through a metered atomized spray pump. The device is made up of a container, a pump and an actuator.

26. Flonase belongs to a class of medications called intranasal corticosteroids that reduce inflammatory reactions that may lead to nasal symptoms such as congestion, sneezing, and itchy, runny nose.

27. Flonase, as acknowledged by GSK in its promotional materials related to the drug, offers unique attributes among allergy medications in that it is non-habit forming and does not cause drowsiness. It is the only drug approved to treat the nasal symptoms of indoor and outdoor allergies as well as year-round nonallergic nasal symptoms.

B. Approval and Sale of Flonase

28. The FDA approved the NDA for GSK's Flonase Nasal Spray (in 50 mcg) for

sale in the United States on October 19, 1994. The agency subsequently approved several supplements to the Flonase NDA in order to add new labeling information, including new indications for use.

29. GSK held a single patent on Flonase which expired on November 14, 2003. Having fulfilled certain requirements regarding pediatric studies, GSK received a six-month extension of market exclusivity from the FDA.[4] Thus GSK's exclusive right to market Flonase in the United States expired on May 14, 2004 and with final approval by the FDA, a generic manufacturer could have begun marketing a generic form of Flonase on or after that date.

30. Prior to entry of generic forms of fluticasone propionate, Flonase held 100% of the relevant market. GSK marketed and sold Flonase in the U.S., yielding annual sales of approximately $930 million in 2004 and over a billion dollars in 2005. The pharmaceutical industry publication *Drug Topics' Top 200 Brand Name Drugs by Dollars* ranked Flonase at number 37 in 2004 and number 33 in 2005.

31. As a sophisticated and long-standing pharmaceutical manufacturer, GSK knew that as its patent exclusivity for Flonase approached, generic manufacturers would seek approval from the FDA to market a generic version of the drug. GSK also knew that such ANDAs would be filed with the FDA in time for the FDA to carefully consider them and issue approval prior to or concomitant with the expiration of GSK's market exclusivity.

C. FDA'S Preparation for Approval of Generic Competition for Flonase

32. Recognizing that it would begin to get ANDAs from manufacturers seeking to

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[4] Section 505A of the FDCA provides for a six-month extension beyond the expiration of the relevant patent during which time an ANDA may not be approved if the FDA determines it desires information about the drug in pediatric populations, and if certain conditions regarding studies of the drug in that populations are met.

market generic versions of nasal aerosol and nasal spray products in the coming years, the FDA initiated a guidance development process in June 1999 to establish a recommended approach for measuring the bioequivalency of those products. Following receipt of comments from the public and the pharmaceutical industry, the FDA reissued the guidance document in draft form in 2003. *See* FDA Draft Guidance, *Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action*, April 2003 ("2003 Draft Guidance").

33. FDA guidance documents simply embody the FDA's current thinking on a subject and provide guidance to the public; they are only recommendations meant to solicit public comment and input. Guidance documents do not bind the FDA and they do not restrict the FDA's ability to consider methodologies or processes other than those articulated in the guidance document. The FDA's obligation to make a determination as to whether an individual ANDA meets statutory requirements and thus should be approved depends in no part on whether or not a guidance document relevant to that ANDA exists. *See generally*, 21 CFR 10.115(d).

34. The FDA approves a multitude of generic drugs without benefit of any relevant guidance document, in draft or final form. If the FDA had to finalize guidance documents prior to taking any relevant administrative action, generic drug approvals stemming from ANDAs would face significant delays. The FDA itself realizes this: "[i]f the FDA were required to answer questions from potential generic drug applicants by issuing guidance documents, it would be impossible for the Agency to fulfill its responsibility under the Act to approve every generic drug that meets the statutory standards." *See* FDA's consolidated response to submissions regarding ANDAs for fluticasone propionate, attached as Exhibit 1, at p. 22 ("FDA's consolidated response").

35. Federal statutes require that in evaluating generic drugs for approval, the FDA must use its own scientific judgment when analyzing bioequivalence data to determine whether there is a "significant difference" in the rate and extent of absorption of the drug between the brand name and proposed generic. Although not bound by its draft guidance documents, the FDA articulated scientifically valid methodologies for making this determination in the 2003 Draft Guidance. The FDA approach to establish bioequivalence for locally acting nasal suspension spray relies on "(1) qualitative and quantitative sameness of formulation of test and reference products, (2) comparability in container and closure systems, and (3) *in vitro* and *in vivo* methods that demonstrate equivalent product performance." *Id*. at p. 5 (citing 2003 Draft Guidance).

36. Product quality standards are also an important consideration for the FDA both for brand name and generic drugs. In 1997, the FDA began recommending that manufacturers seeking approval of nasal sprays include specifications for droplet size distribution ("DSD") and spray pattern ("SP") to help evaluate product quality.

37. Because a nasal spray pump delivers a drug locally (to the nasal mucosa) rather than through the bloodstream, the FDA and manufacturers must consider the amount and method of delivery to the affected area in evaluating the amount of active ingredient provided by each application of the drug. In addition, manufacturers and the FDA must be able to show that, within a certain acceptable variation, each actuation of the nasal pump delivers the same amount of active ingredient to ensure consistent performance over the lifetime of the device. DSD and SP demonstrate, in part, these important considerations.

38. For generic drugs, "the specifications ensure that each production batch of generic… nasal spray meets the standards for drug quality (i.e., delivers clinical performance

per label claims), based on batches that have been demonstrated to be bioequivalent with [the brand name nasal spray]." *Id.* at 21. However, the actual specifications used may differ from manufacturer to manufacturer based on the equipment and testing conditions used. Such differences are perfectly acceptable as long as the products all meet the same standard for product quality.

39. The FDA approved Flonase before it began recommending nasal spray applicants include DSD and SP specifications, but soon requested GSK submit such information. As part of a 1999 supplement to its NDA, GSK submitted specifications for DSD and DS to the FDA. In response, the FDA requested that GSK tighten the acceptable limits and reduce variation in SP and DSD and that GSK test the SP and DSD of each batch of Flonase. In October 2004, the FDA approved final DSD and SP specifications for Flonase based on GSK's reduction in variation in SP and DSD. GSK, with the FDA's knowledge and blessing, continued to sell Flonase as a safe and effective drug during these years.

D. GSK's Unlawful Scheme to Delay Generic Competition for Flonase

40. As the end of its exclusivity period for Flonase neared, GSK knew both that generic manufacturers would be filing ANDAs and that they would do so in time for the FDA to act on them before or by the time GSK's exclusivity period expired.

41. On October 3, 2002, more than a year before GSK's patent expired and more than a year and a half before GSK's statutorily-regulated market exclusivity expired, Roxane filed an ANDA with the FDA seeking approval to market an AB-rated generic version of Flonase upon the expiration of GSK's period of market exclusivity.

42. On May 19, 2004 – just days after the expiration of GSK's Flonase exclusivity and on the eve of what would have been the FDA's approval of Roxane's ANDA – GSK filed

an objectively baseless citizen petition with the FDA for the express purpose, and with the express intent, of delaying the FDA's final approval of any generic manufacturer's ANDA thus delaying generic competition in the United States market for fluticasone propionate. Over the next year, GSK filed additional objectively baseless submissions with the FDA, including a Supplement to the Citizen Petition on November 23, 2004, a Petition for Stay of Action on March 25, 2005, and a Second Supplement to the Citizen Petition on June 16, 2005.

(1) GSK's Citizen Petition

43. On May 19, 2004, five days after its exclusivity period for Flonase expired but more than a year and a half after Roxane filed its ANDA for a generic version of the drug, GSK filed an objectively baseless citizen petition with the FDA. *See* GSK Citizen Petition, dated May 19, 2004, attached as Exhibit 2 ("GSK's First Petition").

44. As stated in the petition, GSK filed the document with the belief that the FDA "may be nearing an approval decision on an ANDA" for generic fluticasone propionate. *Id*. at p. 2.

45. GSK's First Petition did not address the adequacy of Roxane's ANDA, present any evidence that Roxane's fluticasone propionate failed to demonstrate bioequivalence to Flonase, or raise any concerns about public health – the issues for which citizens petitions were primarily implemented. Instead, GSK's First Petition urged the FDA to refrain from approving any AB-rated ANDA for fluticasone propionate until after the FDA completed the process of issuing a *final* guidance document setting forth a scientifically valid methodology for determining bioequivalence for nasal spray products.

46. GSK's citizen petition urged the FDA not to act on any ANDAs for fluticasone propionate until completing the guidance development process, which would presumably include another lengthy period of public comment and the issuance of a final form of the 2003

Draft Guidance. GSK's First Petition argued that prior to approval of any ANDA, the FDA must first develop statistical criteria for *in vitro* and *in vivo* comparative tests, direct that *in vivo* clinical studies be conducted in the "most difficult to treat" indication, and direct that any ANDA applicant conduct certain pharmacokinetic studies. GSK's First Petition at p. 2-3.

47. GSK's First Petition can be called nothing other than a sham. GSK could not reasonably have expected to prevail on the substance of the Petition. Though it purported to be caught unaware that the FDA would even consider approving an ANDA before finalizing the 2003 Draft Guidance, GSK, a sophisticated and long-standing player in the pharmaceutical industry, knew that generic manufacturers would file one or more ANDAs seeking approval to market generic Flonase as soon as GSK's exclusivity for Flonase expired. GSK also knew that the FDA faced no law or regulation requiring it, nor was it FDA's practice, to finalize relevant guidance documents prior to evaluating a pending ANDA or taking other administrative action.

48. As the FDA pointed out in its response to the GSK petition:

> Neither the Act nor the FDA regulations require the FDA to issue final guidance prior to approving an ANDA… GSK has cited no authority to support its position that the Agency must complete a guidance document prior to approving an ANDA for a fluticasone propionate nasal spray product… Whether or not FDA issues final guidance does not speak to the scientific validity of FDA's bioequivalence methodology, scientific evaluation, and approval of generic fluticasone propionate nasal spray products… Over the past eight or more years, based on industry and public input, FDA has developed a scientifically valid methodology capable of detecting a significant difference between test and reference fluticasone propionate nasal spray products.

Exhibit 1: FDA's consolidated response at p. 21-22.

(2) GSK's Supplemental Citizen Petition

49. On November 23, 2004, six months after the filing of GSK's First Petition, GSK submitted a supplemental citizen petition with respect to fluticasone propionate to the FDA.

See GSK's Supplement to the Citizen Petition, dated November 23, 2004, attached as Exhibit 3 ("GSK's Supplemental Petition"). Like its previous submission, GSK's Supplemental Petition neither addressed the adequacy of Roxane's ANDA nor presented any evidence that Roxane's fluticasone propionate failed to demonstrate bioequivalence with Flonase. The petition also failed to raise any concerns about public health.

50. GSK's Supplemental Petition claimed that with respect to product quality, the FDA could not substitute bioequivalence tests as a surrogate for product quality standards. It sought to have the FDA impose on any ANDA filer for fluticasone propionate the same set of standards related to droplet size distribution ("DSD") and spray pattern ("SP") as that imposed by the FDA on GSK's Flonase in October 2004 (supplement S-019 to NDA 20-121).

51. GSK's Supplemental Petition was a sham. GSK could not reasonably have expected to prevail on the substance of the petition. First, prior to GSK's 1999 NDA supplement, and during the entire time GSK worked with the FDA to tighten its SP and DSD parameters, GSK continued to sell Flonase as a safe and effective product. Thus, GSK could not reasonably expect that the FDA would refrain from approving an ANDA that lacked SP and DSD standards. Second, GSK's Supplemental Petition ignored the fact that the FDA had already recommended that all NDA and ANDA applicants for nasal spray products provide specifications for SP and DSD. *See* 2003 Draft Guidance. *See also* FDA's *Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry, Manufacturing, and Controls Documentation*, July 2002.

52. Although the actual specifications for drug quality between ANDA and NDA products may differ, the FDA requires generic and innovator applicants to meet the same standards for product quality. How that quality is measured differs from drug to drug and from

manufacturer to manufacturer due to variations in manufacturing processes, as well as tests developed to measure quality. GSK acknowledged that "A generic drug product need not be manufactured in the same way as the innovator, nor must it necessarily meet identical manufacturing specifications." Exhibit 3: GSK's Supplemental Petition at p. 16.

53. As the FDA pointed out

> [e]ach firm develops its own proprietary product quality tests (e.g., to measure DSD and SP) that may use different equipment under different conditions. Because GSK's DSD and SP product quality tests and methodologies are proprietary, it is virtually impossible for a generic manufacturer to perform the exact same tests that GSK used for Flonase approval to compare test and reference products…. ANDA applicants are not expected to have exactly the same product quality specifications as the [NDA product].

Exhibit 1: FDA's consolidated response at p. 20.

54. When it submitted its supplemental petition, GSK knew and understood the requirements with respect to product quality for nasal spray products previously articulated by the FDA. Given the proprietary nature of quality tests and methodologies GSK had employed with respect to Flonase and the fact that the exact standards imposed on Flonase were dependent in part on those proprietary tests, GSK also understood that it was asking the FDA to impose a nearly impossible standard on any ANDA filer.

(3) GSK's Petition for Stay of Action

55. On March 25, 2005, GSK filed a Petition for Stay of Action seeking "a stay of *just three business days* – beyond the point in time when GSK is first notified of FDA's decision to grant final approval – of the effective date of any approvals FDA may decide to grant of the abbreviated new drug applications… for generic version of Flonase…" Petition for Stay of Action, dated March 25, 2005, Exhibit 4 at p. 1 (emphasis in original) ("GSK's Stay Petition").

56. Federal regulations at 21 CFR 10.35(e) set out the standard for review of a petition for stay of action to the FDA and provide that such a stay may only be granted if the petitioner demonstrates: (1) it will suffer irreparable harm; (2) its case is not frivolous and is being pursued in good faith; (3) it has demonstrated sound public policy grounds supporting the stay; and (4) the delay resulting from the stay is not outweighed by public health or other public interests.

57. Having knowingly failed to provide any legitimate basis in its two prior petitions as to why the FDA should delay approval of any ANDA for generic Flonase and given the FDA's statutory mandate to approve all generic drugs that meet statutory requirements, GSK could not reasonably have expected to prevail in its request for a stay. Instead, GSK submitted the stay application to further hamper efforts to approve the pending ANDA by requiring the FDA to consider and respond to its request.

58. The FDA recognized GSK's Stay Petition as a sham and ruled that "GSK has not articulated sound public policy grounds for supporting a stay." Exhibit 2 at p. 23. The FDA noted that "[a]n assumption underlying GSK's argument is that the Agency's approval standards will, upon further examination, be found inadequate. This assumption is too speculative and too unlikely to form the basis of a public policy argument for grant of a stay." *Id*. Continuing, the FDA observed that "One of the purposes of the Hatch-Waxman Amendments is to foster the availability of low-cost generic drugs. This important public policy would be frustrated if FDA were to grant the stay GSK requests." *Id* at p. 24.

59. The FDA explicitly recognized GSK's attempt to monopolize the market and reprimanded Defendant stating: "[t]he policies behind Hatch-Waxman dictate that GSK should not be permitted to shield its market share when the Agency has reasonably determined that

competing generic drug products may be approved under section 505(j) of the Act." *Id.*

(4) GSK's Second Supplement to the Citizen Petition

60. On June 16, 2005, GSK filed yet another objectively baseless supplement to the citizen petition with the FDA. *See* Second Supplement to Citizen Petition, dated June 16, 2005 attached as Exhibit 5 ("GSK's Second Supplement"). As per course, this petition neither addressed the adequacy of Roxane's ANDA nor presented any evidence that Roxane's fluticasone propionate lacked bioequivalence to Flonase. GSK's Second Supplement similarly failed to raise any concerns about public health. Rather, it included a declaration from a GSK statistician who had reviewed publicly available *in vitro* study data from FDA bioequivalence review of some approved generic nasal solution products, asserting that the FDA inconsistently applied statistical methods for comparative *in vitro* tests for ANDAs for nasal spray *solution* products, a class to which Flonase (a *suspension*) does not belong.

61. Like its other filings, GSK's Second Supplement was a sham and GSK could not reasonably have expected to prevail based on the issues raised in this petition. In the 2003 Draft Guidance, the FDA established that Population Bioequivalence ("PBE") method was appropriate for reviewing and evaluating *in vitro* studies related to nasal spray suspension products. As the FDA's response clearly indicates, the issues raised in GSK's Second Supplement bore no relevance to the FDA's evaluation of fluticasone propionate nasal spray using the PBE methodology already publically identified by the FDA: "GSK's arguments… are not relevant to the fluticasone propionate nasal spray suspension products evaluated under the PBE method." Exhibit 1: FDA's consolidated response at p.11.

D. GSK's Anticompetitive Actions Harmed the Plaintiff and Class Members

62. On February 22, 2006, the FDA rebuffed GSK's various petitions in a 24-page letter, finding the petitions to be without merit. *See* Exhibit 1: FDA's consolidated response. In

the denial, the FDA chastised the company and its motives, writing "GSK is not permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved." But GSK's submissions had had their desired effect and extended the company's monopoly in the United States by nearly two years.

63. On the same date, the FDA issued an approval of Roxane's ANDA for generic Flonase. FDA approval letter to Roxane Laboratories, Inc., dated February 22, 2006, attached as Exhibit 6. After an unsuccessful attempt by GSK to obtain a preliminary injunction overturning the FDA's denial of its citizen petitions and approval of Roxane's ANDA, Roxane began selling generic Flonase in the United States on March 6, 2006 – approximately twenty-two months after GSK's statutorily-granted market exclusivity expired.

64. GSK did not make its series of submissions to the FDA to influence FDA policy or address any legitimate concern about the efficacy or safety of generic fluticasone propionate. Rather, GSK meant solely to forestall generic competition in the United States market for fluticasone propionate during the time it would take the FDA to evaluate and respond to the petitions. GSK, with full knowledge that its exclusivity period for Flonase was approaching expiration and that the FDA was very likely in the process of considering the bioequivalency of one or more generic products, waited until the last possible moment to submit the first of its series of submissions to the FDA, hoping to impose significant delay into the consideration by the FDA of any generic competition. Given the FDA's limited resources and practice at that time of carefully considering all citizen petitions before granting final approval to ANDAs, GSK knew that the filing of a citizen petition would immediately derail the FDA process for approving generic versions of Flonase. GSK made its submissions to the FDA not to influence FDA policy or procedure but instead to delay FDA approval of generic Flonase and unlawfully

extend the company's monopoly for Flonase products in the United States.

65. GSK's unlawful conduct denied Plaintiff and the Class the benefits of free and unrestrained competition in the market for fluticasone propionate from May 19, 2004, the date of GSK's First Petition, until February 22, 2006, the date the FDA approved generic fluticasone propionate for sale in the United States. Further, the effects of GSK's anticompetitive scheme extended beyond February 22, 2006, as the full extent and benefit of generic penetration does not to occur immediately upon generic market entry.

66. GSK's unlawful actions denied Plaintiff and members of the Class the opportunity to purchase lower-priced AB-rated generic versions of Flonase, and thus forced Plaintiff and members of the Class to pay supra-competitive prices for fluticasone propionate.

67. GSK's actions are part of, and in furtherance of, the illegal monopolization scheme alleged herein, and were authorized, ordered or done by GSK's officers, agents, employees or representatives while actively engaged in the management of GSK's affairs.

V. INTERSTATE COMMERCE

68. GSK's efforts to monopolize and restrain competition in the market for fluticasone propionate substantially affected interstate and foreign commerce.

69. At all material times, GSK manufactured, promoted, distributed, and sold substantial amounts of Flonase in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

70. At all material times, GSK transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Flonase.

71. In furtherance of its efforts to monopolize and restrain competition in the market for Flonase and generic forms of Flonase, GSK employed the United States' mails and interstate

and international telephone lines, as well as means of interstate and international travel.

VI. RELEVANT MARKET

72. Direct proof exists that GSK had monopoly power over the price of fluticasone propionate in the United States. Such direct evidence includes transactional data showing a significant, non-transitory decline in prices of fluticasone propionate immediately upon entry of generic versions of the drug. Such a significant, non-transitory decline in prices did not occur until generic entry into the market. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether GSK had monopoly power.

73. GSK, as the only seller of fluticasone propionate products in the United States, could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by GSK's ability to profitably charge supra-competitive prices during the period in which it was without generic competition. There were no reasonably interchangeable drug products available to prescribing physicians for the indications for which fluticasone propionate is prescribed.

74. To the extent that the law requires Plaintiff to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant market is all fluticasone propionate products – *i.e.*, Flonase (in all its forms and dosage strengths) and AB-rated bioequivalent fluticasone propionate products.

75. The relevant geographic market is the United States and its territories.

76. Prior to generic entry in March 2006, GSK held 100% market share in the relevant market. Following market entry by generic manufacturers and much cheaper generic version of Flonase, GSK's market share for fluticasone propionate products declined dramatically in a short period of time.

VII. MARKET EFFECTS

77. GSK's acts and practices, as herein alleged, had the purpose and effect of unreasonably restraining and injuring competition by protecting Flonase from generic competition in the relevant market.

78. Had generic competitors been able to enter the relevant market and compete with GSK, Plaintiff and the Class would have paid for lower-priced generics in place of the higher-priced brand name drug, resulting in far fewer dollars paid for fluticasone propionate products between May 19, 2004 and March 6, 2006, if not beyond. Regulations generally permit – and sometimes even mandate – pharmacists to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. Similarly, many third-party payors of prescription drugs (*e.g.*, managed care plans) encourage or insist on the use of generic drugs whenever possible, thus creating a ready market for generic products.

79. The initial entry of generic products generally leads to a significant erosion of a branded drug's sales within the first year as generic drugs can quickly and efficiently enter the marketplace at substantial discounts. GSK itself recognizes the effects of market entry of generic versions of a drug – both generally and in the specific instance of Flonase competition: affidavits from GSK in its litigation to block entry of a generic version of Flonase state that the company expected to lose $684 million in gross sales during the first six months of generic competition and a total of $1.25 billion in the first year after generic competition began.

80. By preventing generic competitors from entering the market, GSK injured Plaintiff and the other members of the Class in their business or property by causing them to pay more for fluticasone propionate products than they otherwise would have paid. GSK's unlawful conduct deprived Plaintiff and other direct purchasers of fluticasone propionate

products of the benefits of competition that Congress designed federal antitrust laws to preserve.

IX. CLASS ACTION ALLEGATIONS

81. Plaintiff, on behalf of itself and the proposed Class, seeks monetary damages against GSK based on allegations of anticompetitive conduct in the market for Flonase and its AB-rated generic equivalents.

82. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a), (b)(2) and (b)(3), as representative of a Class defined as follows:

> All persons or entities in the United States and its territories who purchased and/or paid for Flonase nasal spray directly from GSK (or any of its predecessors or affiliates) at any time from May 19, 2004 until the anticompetitive effects of Defendant's conduct ceased (the "Class").

Excluded from the Class are GSK, and its predecessors, officers, directors, management, employees, subsidiaries, parent or affiliates, and all federal governmental entities.

83. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes there are at least hundreds of Class members spread across the United States. Moreover, members of the Class are readily identifiable from information and records that are in the possession of GSK.

84. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged in the same way by the same wrongful conduct of GSK, i.e., they paid artificially inflated prices for fluticasone propionate and were deprived of the benefits of competition from cheaper generic versions of Flonase as a result of GSK's wrongful conduct.

85. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

86. Plaintiff is represented by counsel who are experienced and competent in the

prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

87. Questions of law and fact common to the members of the Direct Purchaser Class predominate over questions, if any, that may affect only individual Class members because GSK has acted on grounds generally applicable to the entire Class thereby making monetary and equitable relief with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in GSK's wrongful conduct.

88. Questions of law and fact common to the Class include:

a. whether GSK delayed or prevented generic manufacturers from coming to market in the United States;

b. whether the petitioning to the FDA by GSK was objectively baseless;

c. whether GSK maintained its monopoly power by improperly delaying generic entry through, *inter alia,* the filing of sham citizen petitions with the FDA;

d. whether direct proof of GSK's monopoly power is available, and if available, whether it is sufficient to prove GSK's monopoly power without the need to also define a relevant market;

e. to the extent a relevant market or markets must be defined, what that definition is;

f. whether the activities of GSK as alleged herein have substantially affected interstate commerce; and

g. whether, and to what extent, GSK's conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class, and if so, the appropriate measure of damages.

89. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the

unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

90. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. CLAIM FOR RELIEF: MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT

91. Plaintiff repeats, and incorporates by reference, the allegations in ¶¶ 1 – 90 above.

92. GSK used willful and exclusionary means as part of an overall scheme described herein to improperly maintain and extend its monopoly power in the fluticasone propionate market, as described above. GSK accomplished this scheme by filing baseless citizen petitions with the FDA in an attempt to delay generic versions of Flonase from entering the market.

93. The goal, purpose and effect of GSK's scheme was to prevent, delay, and/or minimize the success of the entry of AB-rated generic fluticasone propionate which would have sold in the United States at prices significantly below GSK's prices for Flonase, thereby effectively causing the average market price of fluticasone propionate to decline dramatically.

94. The goal, purpose and effect of GSK's scheme was also to maintain and extend its monopoly power with respect to fluticasone propionate. GSK's illegal scheme enabled GSK to continue charging supra-competitive prices for fluticasone propionate, without a substantial loss of sales, reaping substantial unlawful monopoly profits.

95. Plaintiff and members of the Class purchased substantial amounts of Flonase

directly from GSK.

96. As a result of GSK's illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, more than they would have paid for fluticasone propionate absent GSK's illegal conduct. But for GSK's illegal conduct, competitors would have begun marketing generic versions of Flonase well before they actually did.

97. Had manufacturers of generic fluticasone propionate entered the market and lawfully competed with GSK in a timely fashion, Plaintiff and other members of the Class would have substituted lower-priced generic fluticasone propionate for the higher-priced brand name Flonase for some or all of their fluticasone propionate requirements, and/or would have paid lower net prices on their remaining Flonase purchases.

98. As a consequence, Plaintiff and the Class have sustained damage to their business and property in the form of overcharges. The injury to Plaintiff and the Class is the type of injury antitrust laws were designed to prevent, and the injury flows from GSK's unlawful conduct.

99. GSK's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for fluticasone propionate in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

IX. JURY TRIAL DEMANDED

100. Plaintiff demands trial by jury on all issues so triable.

X. DEMAND FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Class, respectfully requests that:

a. The Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;

b. The acts alleged herein be adjudged and decreed to be unlawful and willful acts of monopolization in restraint of trade in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2,

c. The Class be awarded three-fold the damages determined to have been sustained by the Class, and that judgment be entered against Defendant in favor of the Class;

d. The Class recover their costs of suit, including reasonable attorneys' fees as provided by law; and

e. The Class be granted such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Respectfully submitted,

/s/ JHM6596

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